Award Number:
W81XWH-11-1-0641

TITLE:
Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD

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REPORT DATE: Oct 2015

TYPE OF REPORT:
Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	**2. REPORT TYPE**	**3. DATES COVERED**
October 2015	Annual	15 Sep 2014 – 14 Sep 2015

4. TITLE AND SUBTITLE
Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-11-1-0641

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Veterans Medical Research Foundation
3350 La Jolla Village Dr. (151A)
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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
This study is a randomized trial of a hybrid treatment for Iraq and Afghanistan Veterans with a history of mild to moderate TBI (mTBI) and PTSD. Emotional symptoms are likely a main cause of the persistence of post-concussive symptoms while thinking problems and emotional control problems associated with mTBI can impede recovery from PTSD. However, there is no PTSD treatment specifically designed to accommodate the difficulties with attention, memory, and problem solving that patients with TBI may have. Therefore, this study integrates therapeutic approaches and tests a modification of cognitive processing therapy (CPT), an empirically supported treatment for PTSD, in which CPT is enhanced with compensatory cognitive rehabilitation principles. The enhanced CPT, called SMART-CPT is being compared to standard CPT in a group of Iraq and Afghanistan Veterans with a history of both mTBI and PTSD. Half of the participants are randomly assigned to receive standard CPT and half to receive SMART-CPT. This year was dedicated recruitment, enrollment, and treatment, with 94 Veterans enrolled and 45 who have completed all treatment sessions, to date.

15. SUBJECT TERMS
TBI, PTSD, cognitive rehabilitation, CPT

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRMC
U	U	U	UU	9	**19b. TELEPHONE NUMBER** *(include area code)*

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INTRODUCTION:

This study focuses on helping Iraq and Afghanistan Veterans who have a history of mild to moderate traumatic brain injury (TBI) and posttraumatic stress disorder (PTSD) benefit fully from interventions for both conditions. PTSD and TBI occur together frequently in Iraq and Afghanistan Veterans, a combination of conditions which often complicates recovery from either condition. Emotional symptoms are likely a main cause of the persistence of post-concussive symptoms while thinking problems and emotional control problems associated with mild to moderate TBI can impede recovery from PTSD. Prior research has shown that cognitive rehabilitation programs that focus on teaching about what is typical after a head injury, providing people with expectation of positive recovery, and teaching strategies that allow individuals to compensate for their cognitive deficits are effective for treating the thinking symptoms resulting from mild to moderate TBI. These practice standards have been organized into a manualized treatment, Cognitive Symptom Management and Rehabilitation Therapy (CogSMART), which teaches veterans ways to compensate for cognitive difficulties. Psychotherapies that focus on changing thoughts and behaviors related to a traumatic event, such as Cognitive Processing Therapy (CPT), are effective treatments for PTSD and are the standard of care for treatment of the disorder. However, there is no PTSD treatment specifically designed to accommodate the difficulties with attention, memory, and problem solving that patients with TBI may have. Therefore, this study integrates therapeutic approaches and tests a modification of CPT in which CPT is enhanced with compensatory cognitive rehabilitation principles detailed in CogSMART. The enhanced CPT, called SMART-CPT will be compared to standard CPT in a group of Iraq and Afghanistan Veterans with a history of both mild to moderate TBI and PTSD. Half of the participants will be randomly assigned to receive standard CPT and half to receive SMART-CPT.

BODY:

September 15, 2014 to September 14, 2015 was the fourth fiscal year of the Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD study. The focus in the fourth fiscal year was on recruitment, enrollment, assessment, and treatment.

The following are accomplishments as outlined in the Statement of Work:

Task 1. Study Start Up, Months 1-12: Complete, see prior annual report.

Task 2. Recruitment, Enrollment and Treatment and Assessment, months 13-40, extended with a one year no-cost extension through month 50:

2a. Ongoing recruitment of participants:

In the fourth fiscal year of this study, the study coordinator has attended meetings in VA-based TBI and PTSD treatment clinics and has been in frequent contact with other study coordinators to facilitate study recruitment. We have also contacted our local Vet Centers as additional recruitment avenues and disseminated study brochures more widely to other relevant clinics within the VA (e.g., Member Services, Polytrauma, Social Work). The study coordinator

has also responded to a steady flow of referrals from clinical providers within the PTSD clinics in the La Jolla, Mission Valley and Oceanside VA locations. In addition, the study coordinator worked closely with the Polytrauma Clinic at the VA to build a more efficient system to reach Veterans who are interested in participating in research.

The tables below depict recruitment efforts for the third fiscal year as well as recruitment to date. 'Pending referrals' are typically referred individuals with whom we have ongoing efforts to contact or who have expressed interest in enrolling but need to wait for medication stabilization or other scheduling issues.

Recruitment in fourth fiscal year:

Total Referrals	Enrolled	Pending	Declined/ Do not qualify
272	26	27	219

***Total* recruitment through fourth fiscal year:**

Total Referrals	Enrolled	Pending	Declined/ Do not qualify
513	94	27	392

2b. Treatment:

Of the 26 participants enrolled in the fourth fiscal year, 20 participants have started treatment. To date, 48 participants have been randomized to the SMART-CPT condition and 46 to the standard CPT treatment group. To date, 27 participants have completed all aspects of the study, including all treatments and assessment sessions (including extended post-treatment assessment). Forty-five participants have completed all 12 therapy sessions. Overall, 46% of participants have not continued treatment to the completion of the study. Fidelity checks of therapy sessions are proceeding on schedule and Dr. Boyd, the study psychologist, continues to meet weekly with Dr. Rodgers for supervision regarding the study treatments. We have not had a serious adverse event in the fourth year of this project.

2c. Assessment:

In the fourth fiscal year all who were enrolled completed pre-treatment assessments, eight post-treatment assessments, and 11 extended follow-up assessments. To date, 92 enrolled participants have undergone the pre-treatment assessment consisting of neuropsychological, mood, and symptom ratings. Thirty-nine participants have undergone the post-treatment assessment, and 27 have completed the extended follow-up assessment and fully completed the study. All assessments continue to be double-scored and double-entered into the database to insure accuracy in administration, scoring, and data entry and that any errors are not perpetuated.

Preliminary data analysis to determine initial response to and tolerability of treatment reveals that those Veterans in the standard CPT group had starting PCL scores of 59.68 and ending PCL scores of 38.11 (average change of 21.6 points). Veterans in the SMART-CPT group had starting PCL scores of 57.58 and ending PCL scores of 41.04 (average change of 16.5 points). This data establishes that the treatment results in clinically significant change in PTSD symptoms and that adding cognitive rehabilitation principles to standard CPT does not 'dilute'

the treatment for PTSD in any way. The non-completion rate is equivalent between groups, however, of those who do not complete the treatment, the SMART-CPT group completes, on average, two more sessions before dropping out than those from the CPT group. Because one concern regarding using CPT in populations with cognitive complaints is early drop-out, these preliminary results are encouraging and suggest that the hybrid SMART-CPT approach is able to enhance treatment session completion in comborbid PTSD and TBI.

KEY RESEARCH ACCOMPLISHMENTS:

- All regulatory approvals were renewed and are current and up to date.
- 94 Veterans have been enrolled in the trial to date
- 92 Veterans have completed baseline assessment
- 39 Veterans have completed all active components of the protocol
- 27 Veterans have completed all components of the study (which includes the extended follow-up)

REPORTABLE OUTCOMES:

- Post-doctoral fellow, Dr. Crocker, on behalf of Dr. Jak, was accepted to present at the Anxiety and Depression Association of America 2015 Conference in April, 2015 in Miami, Florida on the SMART-CPT study in a symposium entitled **"**Addressing the Needs of Combat Veterans With Co-occurring Head Injury and Mental Health Symptoms: Clinical Trial Outcomes for Individuals With TBI and Psychological Stress." The symposium presenters include: Grant Iverson, PhD; Eric Crawford, PhD; Laura Crocker, PhD; Rebecca Sripada, PhD; Jessica Bomyea, PhD; Ariel Lang, PhD.
- At the INS 43rd Annual Meeting on February 4-7, 2015 in Denver, Colorado, Dr. Jak presented "Neuropsychological performance in treatment seeking OEF/OIF/OND Veterans with a history of mild TBI" as an oral paper presentation and graduate student Sarah Jurick presented the poster: "Mental Health Treatment Reduces Post-concussive Symptoms and Symptom Overreporting in Iraq and Afghanistan Veterans.
- The manuscript resultant from the aforementioned paper session is now accepted for publication at the *Journal of Clinical and Experimental Neuropsychology*.
- Post-doctoral fellow, Dr. Crocker, on behalf of Dr. Jak, was invited to submit an abstract to the International Society for Traumatic Stress Studies (ISTSS) 2015 Annual Meeting in New Orleans on the SMART-CPT study as part of a symposium entitled "Effectiveness of Cognitive Training and Psychotherapeutic Interventions for Improving Neurocognitive Outcomes in Patients with PTSD." The Jak lab submitted the following which is under review: "Combining Cognitive Processing Therapy and Cognitive Rehabilitation to Streamline Treatment of Veterans with Comorbid PTSD and TBI."
- Boyd, B., Rodgers, C., Aupperle, R., & **Jak, A.J.** (accepted for publication). Case Report on the effects of Cognitive Processing Therapy on Psychological, Neuropsychological and Speech Disturbances in Comorbid PTSD and TBI. To appear

in *Cognitive and Behavioral Practice.*

- **Jak, A.J.,** Aupperle, R., Rodgers, C., Lang, A.J., Schiehser, D., Norman, S.B., & Twamley, E.W. (under review). Evaluation of a hybrid treatment for veterans with comorbid traumatic brain injury and posttraumatic stress disorder: study protocol for a randomized controlled trial.

CONCLUSION:

In summary, "Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD", is proceeding generally on schedule and most tasks detailed in the statement of work, including maintaining regulatory approvals, recruitment efforts, assessments, and treatment; our drop-out rate is higher than anticipated, however. Due to the higher than expected drop-out rate, we requested a one year no-cost extension in April 2015. In order for the Veterans who were enrolled by June 2015 to be able to finish all aspects of the study, we temporarily halted recruitment while awaiting approval of the NCE. Upon confirmation of the one year NCE in August 2015, we resumed recruitment. Despite this delay, we were able to enroll 26 Veterans in the 4th fiscal year of the study for a total of 94 Veterans enrolled across all years of the project. In the fourth year, we have not encountered any serious adverse events. Preliminary examination of the data revealed clinically significant reductions in PTSD symptoms in both treatment groups. Of those who did drop out of treatment, the SMART-CPT group completed two more sessions before dropping out than those from the CPT group. Work supported by this award has also led to three presentations and two publications this fiscal year.

While our recruitment and enrollment has been consistent with our proposed rate in the SOW, we have experienced a higher than expected attrition rate (46%). Although high, it is nonetheless well aligned with dropout rates reported in the literature for OEF/OIF Veterans, in particular (e.g., Chard, et al., 2010). It also reflects difficulties with treatment dropout noted by an Institute of Medicine Report (Treatment for Posttraumatic Stress Disorder in Military and Veteran Populations: Initial Assessment, 2012) that may be related, in part, to high rates of comorbidities in the target population as well as trauma-related avoidance. We have targeted a representative treatment seeking sample by including those individuals with relatively recent sobriety and mental health comorbidities, and do not exclude participants based solely on the presence of suicidal ideation. This results in a more challenging, though realistic, treatment sample. All of these factors are likely contributing to the attrition rate and are concerns we are actively working to overcome. Although the dropout rate is not different between the two treatment conditions in this study, those in the experimental SMART-CPT arm, which targets comorbid post-concussive symptoms, continue to remain in treatment longer (average 8.6 sessions) than those in standard CPT (average 6.6 sessions), suggesting that concurrently addressing comorbidities can improve treatment adherence. Because we were otherwise on schedule with recruitment and had sufficient budgetary funds, we requested and received a one year no-cost extension to over-recruit and over-enroll as needed over the next fiscal year to meet our desired usable sample of 72 participants. Tasks detailed in the SOW for the fourth fiscal year will now be completed in fiscal year 5.

REFERENCES:

Chard, K.M., Schumm, J.A., Owens, G.P., and Cottingham, S.M. (2010). A comparison of OEF and OIF veterans and Vietnam veterans receiving cognitive processing therapy. *Journal of Traumatic Stress, 23*, 25-32.

APPENDICES:

None at this time.